

## REMARKS

Claims 109-112 and 114-118 remain in the application.

Claims 117 and 118 are a rewriting of allowable claims 101 and 110 in independent form, and with revisions that overcome the rejections under 37 U.S.C. § 112, ¶ 2, to claims 97, 101 and 109. Therefore, claims 117 and 118 are now in condition for allowance.

Claim 109 was rejected under 35 U.S.C. § 112, ¶ 1, as failing to comply with the enablement and written description requirements. Applicants' attorney requested clarification of this rejection in a telephone conversation with Examiner Corcoran on July 23, 2004. As explained hereafter, the disclosure as well as original claims 1-32 fully support the claim recitations, and satisfy both the enablement and written description requirements.

Claim 109 recites the erection of a tray in an erection mold, and attachment of a collar to the erected tray while it is positioned in an assembly mold that may be the same as the erection mold or may be a different mold that has the same configuration as the erection mold.

FIG. 16 and lines 7-19 on page 24 show and describe an erection mold 316 in which a tray blank 40 of FIG. 3 is erected to form the tray of FIG. 6. FIG. 16 also shows the collar mold 318 that cooperates with the mold 316 to position and bond the collar of FIGS. 3 and 4 to the tray peripheral sidewall and provide the tray with an outwardly extending flange 52. The assembled trays and collars are loaded in a magazine 112 in FIG. 1 from which they are discharged to be lined with a plastic film, filled with desired contents and sealed.

FIG. 17 and lines 19-28 on page 24 show and describe "a somewhat modified configuration of the trays." The same numbers that are used to reference the various parts of the

tray blank and tray in FIGS. 5 and 6 are used to reference the various parts of the tray in FIG. 17 with the addition of a "4" ahead of the numbers in FIG. 17. The only modification to the tray part is that the tray part sidewall in FIG. 17 has added flange segments 444. The only other modification to the entire assembled tray is that the flange forming collar 452 that is used with the tray of FIG. 17 does not have the tabs 51 like the flange forming collar of FIGS. 3 and 4.

It is plain that reference to the tray of FIG. 17 as being a modification of the tray would be understood to mean that the FIG. 17 tray is a modification of the tray in FIGS. 5 and 6 that is erected in a mold as shown and described with reference to FIG. 16. It is inconceivable that a person of ordinary skill in the art would be dumbfounded as to how to erect the tray of FIG. 17, and would not understand that it also could be erected in a mold in the same manner as the tray that it is a modification of.

FIG. 18, and lines 30-36 on page 24 and 1-6 on page 25, show and describe loading a magazine 512 with erected trays 510 that do not yet have collars attached thereto. The erected trays 510 are individually fed from the magazine and provided with flange segments 444 of FIG. 17 by way of plug member 517. The collar 452 of FIG. 17 is then attached to the tray at the station KS in FIG. 18 which illustrates molds having the same configuration as the molds in FIG. 16.

Insofar as the rejection is understood, it is the Examiner's view that there is a written description and/or enablement only for attaching the collar to the tray while the tray is held in the identical mold in which it was erected.

With respect to attaching the collar to the tray while it is held in a mold that has the same internal configuration as the erection mold, but is not necessarily the same mold in which the

tray was erected, the Examiner's apparent position is that there is no disclosure of how-to-do-it, and/or that a person of ordinary skill in the art would not recognize that applicants were in possession of the knowledge necessary to practice the claimed invention by using erection and assembly molds that are not the same but that have the same configuration.

The Examiner appears to have an extreme and unreasonable view of the enablement and written description requirements. In the Examiner's view, the specification fails the enablement and written description requirements for anything and everything that is not specifically stated. Thus, because there is no specific statement in the specification that the tray of FIG. 17 is erected in a mold like the tray of FIGS. 5 and 6 that it modifies, the specification must fail the enablement and written description requirements for a claim that would cover erection of the FIG. 17 tray in a mold.

The Examiner is applying a standard that is not even applicable to emerging and unpredictable technologies, and is entirely inappropriate for the mature subject matter of the present application.

"The written description requirement does not require the applicant to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." Union Oil Co. of Cal. v. Atlantic Richfield Co., 208 F.3d 989, 997 54 USPQ2d 1227, 1232 (Fed. Cir. 2000). "Thus, an inventor is not required to describe every detail of his invention. An applicant's disclosure obligation varies according to the art to which the invention pertains." In re Hayes Microcomputer Products Inc. Patent Litigation, 982 F.2d. 1527, 1534-35, 25 USPQ2d 1241, 1246 (Fed. Cir. 1992). Also, see page 9 of the article attached in the Appendix, "Written Description

and Patent Examination Guidelines Under the U.S. Patent and Trademark Office Guidelines," by Scott A. Chambers:

"Generally, there is an inverse correlation between the level of skill and knowledge in the art and the amount of disclosure necessary to satisfy the written description requirement. As a technology becomes more mature, less evidence is required to show possession."

What is conventional or well-known to one of ordinary skill in the art need not be disclosed in detail. "If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met." See attached page 15 of the Guidelines for Examination of Patent Applications Under the 35 U.S.C. §112, ¶ 1, Written Description Requirement. Also, it is fundamental that the drawings alone can be sufficient to satisfy the written description requirement.

"Whether the specification shows that applicant was in possession of the claimed invention is not a single, simple determination, but rather is a factual determination reached by considering a number of factors. Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." See pages 15 and 16 of the attached Guidelines.

Originally filed claims 1-32 also provide support for erecting the tray of FIG. 17 in a mold. Original claim 1 includes reference numbers for both the tray of FIGS. 5 and 6, and the tray of FIG. 17. There can be no doubt that original claim 1 encompasses both trays. Original claim 23 depends from claim 1 and further recites the collar that is positioned on the tray. Claim 30 depends from claim 23 and recites the erection in a mold of the tray that is recited in the parent claims, including claim 1. Because original claim 1 recites the tray of FIG. 17, and claim 30 recites the erection in a mold of the tray(s) of claim 1, the original claims provide clear support for the present claims, and a person of ordinary skill in the art could not possibly fail to recognize that the inventors were in possession of the invention as claimed in claim 109.

The Examiner has not adequately explained the reasons why a person of ordinary skill in the art would not recognize in the present disclosure and originally filed claims a description of the invention defined by the claims. The only "reason" given by the Examiner is that there is no specific statement that the tray of FIG. 17 is erected in a mold (which ignores original claims 1, 23 and 30). That is no reason at all, and if this rejection is maintained, there must be detailed reasons or evidence provided as to why a person of ordinary skill in the art would be so unskilled as to fail to recognize that even the erected trays of FIG. 16 could be transferred to a different mold of the same configuration as the erection mold for attaching the collar. Thus, one of ordinary skill in the art would be aware that the erected but unflanged trays of FIGS. 5, 6 and 16 could be loaded in the magazine 512 of FIG. 18 and then be provided with the collar/flange at the station KS in FIG. 18 by using a mold that has the *same configuration* as the mold of FIG. 16, but not necessarily the *same mold*.

The art rejection on Anderson et al taken with Bemish is not well taken. The tray blank of the present application has segmented sidewall portions that enable erection of the tray in a


mold because the sidewall segments simply overlap one another when the tray is erected in the mold.

U.S. Patent No. 4,019,675 to Anderson et al does not disclose a tray blank that is capable of being erected in a mold. The lines in the Anderson et al blank of FIG. 1 are fold lines and it is plain from the erected tray of FIGS. 2 and 4 as to how the blank is folded. The fold line that extends generally radially between each pair of corner segments 6, 6 must be folded *outwardly*, and this precludes erection in a mold. After the segments 6, 6 are folded into engagement with one another along the radial fold line between them, the segments 6, 6 that now overlies one another are again folded along the fold lines between the tray sides 3, 5 and the adjacent segment 6 into engagement with the exterior surfaces of the tray ends 2, 4 as shown in FIGS. 2, 4, 7, 8, 11 and 12. Anderson et al does not teach or suggest erection of the tray in a mold, and no prior art suggests modifications to the Anderson et al tray that would make it capable of being erected in a mold. Therefore, the rejection of claims 109-12 and 114-116 must be withdrawn.

U.S. Patent No. 3,104,012 to Bemish adds reinforcing strips to the *external* corners of a tray, and does not suggest attachment of the Anderson et al collar 12 to the tray sidewall by using a mold. The Anderson et al collar 12 has its curved corners cantilevered inwardly of the open mouth of the tray. See lines 45-54 of column 1 and lines 29-37 explaining that the collar corners span the tray corners to provide an undercut for snap reception of a cover as shown in FIG. 5A. This is not conducive to attachment of the collar by using a mold because the mold could not closely fit within the tray to hold it in position during collar attachment as it would have to be spaced from the corners of the tray where they are spanned by the collar.

For the above reasons, the rejections under 35 U.S.C. § 112 must be withdrawn because one skilled in the art clearly would understand from the disclosure and original claims that applicants were in possession of the knowledge necessary to practice the claimed invention by using erection and assembly molds that are not necessarily the same but that have the same configuration. Also, Anderson et al does not disclose or suggest a tray blank that is capable of erection in a mold.

Respectfully submitted,

  
H. Duane Switzer  
Reg. No. 22,431  
Jones Day  
North Point  
901 Lakeside Avenue  
Cleveland, OH 44114-1190  
216-586-7283

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Appendix:



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[Notices]

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DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No. 991027288-0264-02]

RIN 0651-AB10

Guidelines for Examination of Patent Applications Under the 35  
U.S.C. 112, para. 1, "Written Description" Requirement

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: These Guidelines will be used by USPTO personnel in their review of patent applications for compliance with the "written description" requirement of 35 U.S.C. 112, para. 1. These Guidelines supersede the "Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1 "Written Description" Requirement" that were published in the Federal Register at 64 FR 71427, Dec. 21, 1999, and in the Official Gazette at 1231 O.G. 123, Feb. 29, 2000. These Guidelines reflect the current understanding of the USPTO regarding the written description requirement of 35 U.S.C. 112, para. 1, and are applicable to all technologies.

DATES: The Guidelines are effective as of January 5, 2001.

FOR FURTHER INFORMATION CONTACT: Stephen Walsh by telephone at (703) 305-9035, by facsimile at (703) 305-9373, by mail to his attention addressed to United States Patent and Trademark Office, Box 8, Washington, DC 20231, or by electronic mail at [stephen.walsh@uspto.gov](mailto:stephen.walsh@uspto.gov); or Linda Therborn by telephone at (703) 305-8800, by facsimile at (703) 305-8825, by mail addressed to Box

quirements of 37 CFR 1.801 et seq.\38\

An applicant may show possession of an invention by disclosure of drawings \39\ or structural chemical formulas\40\ that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. The description need only describe in detail that which is new or not conventional.\41\ This is equally true whether the claimed invention is directed to a product or a process.

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics \42\ which provide evidence that applicant was in possession of the claimed invention.\43\ i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.\44\ What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail.\45\ If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met.\46\

(1) For each claim drawn to a single embodiment or species: \47\  
(a) Determine whether the application describes an actual reduction to practice of the claimed invention.

(b) If the application does not describe an actual reduction to practice, determine whether the invention is complete as evidenced by a reduction to drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole.

(c) If the application does not describe an actual reduction to practice or reduction to drawings or structural chemical formula as discussed above, determine whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention.

(i) Determine whether the application as filed describes the complete structure (or acts of a process) of the claimed invention as a whole. The complete structure of a species or embodiment typically satisfies the requirement that the description be set forth "in such full, clear, concise, and exact terms" to show possession of the claimed invention.\48\ If a complete structure is disclosed, the written description requirement is satisfied for that species or embodiment, and a rejection under 35 U.S.C. 112, para. 1, for lack of written description must not be made.

(ii) If the application as filed does not disclose the complete structure (or acts of a process) of the claimed invention as a whole, determine whether the specification discloses other relevant identifying characteristics sufficient to describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention.\49\

Whether the specification shows that applicant was in possession of the claimed invention is not a single, simple determination, but rather is a factual determination reached by considering a number of factors. Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other

materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. \50\ Patents and printed publications in the art should be relied upon to determine whether an art is mature and what the level of knowledge and skill is in the art. In most technologies which are mature, and wherein the knowledge and level of skill in the art is high, a written description question should not be raised for original claims even if the specification discloses only a method of making the invention and the function of the invention. \51\ In contrast, for inventions in emerging and unpredictable technologies, or for inventions characterized by factors not reasonably predictable which are known to one of ordinary skill in the art, more evidence is required to show possession. For example, disclosure of only a method of making the invention and the function may not be sufficient to support a product claim other than a product-by-process claim. \52\ Furthermore, disclosure of a partial structure without additional characterization of the product may not be sufficient to evidence possession of the claimed invention. \53\

Any claim to a species that does not meet the test described under at least one of (a), (b), or (c) must be rejected as lacking adequate written description under 35 U.S.C. 112, para. 1.

(2) For each claim drawn to a genus:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see (1)(a), above), reduction to drawings (see (1)(b), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see (1)(c), above). \54\

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. On the other hand, there may be situations where one species adequately supports a genus. \55\ What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. \56\ Description of a representative number of species does not require the support for each species that the genus embraces. \57\ If a representative number of adequately described species are not disclosed for a genus, the claim to that genus must be rejected as lacking adequate written description under 35 U.S.C. 112, para. 1.

b. New claims, amended claims, or claims asserting entitlement to the benefit of an earlier priority date or filing date under 35 U.S.C. 119, 120, or

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365(c). The examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize

## "Written Description" and Patent Examination Under the U.S. Patent and Trademark Office Guidelines

By: Scott A. Chambers

(This first appeared in the September/October 2000 issue of *IP Litigator*.)

The written descriptions for inventions named in an original disclosure were taken for granted in the past. If there was an enabling disclosure, the examiner would not question the compliance of 35 U.S.C. § 112, first paragraph for an originally disclosed claim. The Reagents of the University of California v. Eli Lilly,<sup>1</sup> taken with Fiers v. Revel<sup>2</sup> and Amgen, Inc. v. Chugai Pharmaceutical Co.<sup>3</sup> suggest this is no longer true. Moreover, In re Bell<sup>4</sup> and In re Deuel<sup>5</sup> may have mandated the Eli Lilly result. Consequently, this robust interpretation of the written description requirement may be here to stay. While some practitioners may not have agreed with the evolving nature of the written description requirement, practitioners and the Patent and Trademark Office (PTO) cannot ignore the law as interpreted by the Court of Appeals for the Federal Circuit and must respond in a manner that continues to protect the intellectual property interests of their clients. Moreover, the Federal Circuit's clarification of the written description requirement suggests some broadly drawn patents may be vulnerable to attack for lack of written description.

### Statutory Basis

The Written Description requirement is found in Section 112, paragraph 1 of title 35, which states:

The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Past Federal Circuit case law has held that written description is separate and distinct from the definiteness<sup>6</sup> and enablement<sup>7</sup> requirements of the Patent Act. However, nearly all of the case law from the Federal Circuit and its progenitors interpreting the written description requirement was directed to whether there was support for claims added after filing: at issue was whether new matter or additional information was added after the filing date.

likely than not that the applicant was in possession of the claimed invention. These can include complete or partial structure, physical or chemical properties, functional characteristics when they say something about the structure, or even a method of making a claimed product.

Generally, there is an inverse correlation between the level of skill and knowledge in the art and the amount of disclosure necessary to satisfy the written description requirement. As a technology becomes more mature, less evidence is required to show possession. } ✓

For claims asserting an entitlement to an earlier filing date as well as new and amended claims, the examiner must determine that each claim limitation is expressly, implicitly, or inherently supported in the originally filed disclosure.<sup>xxiv</sup> The examiner is instructed to make sure that each claim includes all of the elements that the applicant describes as essential of critical.<sup>xxv</sup> In some situations, minor sequencing errors may be corrected by reliance on a biological deposit. This is an important consideration because sequencing errors are quite common in biotechnology. Assuming that a proper descriptive fingerprint exists for the deposit, the amendment should not be new matter because it is simply adding an inherent aspect of an already known invention.<sup>xxvi</sup> One of skill in the art could simply retrieve the deposited microorganism, recognize the error in sequencing, and identify the correct sequence. However, biological deposit does not substitute for a written description of the invention.

For genus species claims, evidence of possession is first analyzed for each claim drawn to a species, and thereafter for each claim drawn to a genus. Written description for a claimed genus may be satisfied through description of a representative number of species. A representative number should not be confused with a predictive number. It is unnecessary for an applicant to provide enough species that the disclosure will permit one of skill to determine a sequence from the application alone. Indeed, the stochastic nature of gene evolution would make such predictability impossible for nucleic acid inventions and it is unlikely the Federal Circuit wanted to change patent law in this manner.

#### Revised Utility Guidelines

During the comment period, the PTO received numerous suggestions and assertions that a particular type of application directed to expressed sequence tags was unpatentable due to a lack of written description. After analyzing these assertions in some detail, it was determined that disclosure of a precise sequence—such as an EST—and claims to that sequence did not